

Why GAO Did This Study

FDA is responsible for ensuring the safety and effectiveness of all drugs marketed in the U.S., regardless of where they are produced.

Globalization—and the outbreak of COVID-19—have complicated FDA's oversight of the more than 4,000 establishments manufacturing drugs for the U.S. HHS reported that 73 percent of establishments manufacturing active ingredients, and 52 percent of those manufacturing finished drugs for the U.S., were located overseas as of March 2021.

GAO's concerns about FDA's ability to oversee the increasingly global drug supply chain led it to designate the issue as a high risk area in 2009. GAO was asked to update its work on FDA's foreign drug inspection program. This report (1) describes the number of inspections prior to and during the COVID-19 pandemic, (2) examines steps taken to address challenges related to preannouncing foreign inspections and language barriers, and (3) examines efforts to maintain a sufficient inspection workforce, among other objectives. For this work, GAO examined FDA data and documents and interviewed drug investigators and other FDA officials. GAO also visited FDA foreign offices in China and India in fall 2019.

What GAO Recommends

GAO is making three recommendations: that FDA incorporate leading practices into the design of both its unannounced inspection and translation pilot programs and fully develop tailored strategies to ensure it has a sufficient foreign inspection workforce. HHS agreed with GAO's recommendations.

View [GAO-22-103611](#). For more information, contact Mary Denigan-Macauley at (202) 512-7114 or deniganmacauleym@gao.gov.

DRUG SAFETY

FDA Should Take Additional Steps to Improve Its Foreign Inspection Program

What GAO Found

In fiscal year 2019, the Food and Drug Administration (FDA) began to increase the number of inspections of foreign drug manufacturing establishments after decreases from fiscal years 2016 through 2018. FDA, an agency within the Department of Health and Human Services (HHS), conducts the largest number of foreign inspections in India and China, where more than one-third of foreign establishments supplying the U.S. market are located. However, beginning in March 2020, FDA postponed most inspections because of the COVID-19 pandemic, conducting three foreign inspections from March to October 1, 2020. In comparison, FDA conducted more than 600 foreign inspections over the same time period in each of the 2 prior years. From October 2020 to April 2021 (the most recent period for which data are available), FDA conducted 18 high priority foreign inspections—primarily in China. In November 2021, FDA announced it was developing plans to potentially resume foreign inspections in February 2022.

GAO has reported that FDA faces unique challenges conducting foreign inspections—including that inspections have generally been preannounced and that investigators may rely on the establishment being inspected to provide translation services. While drugs manufactured overseas for the U.S. market must meet the same requirements as those manufactured in the U.S., these unique challenges raise questions about the equivalence of foreign to domestic inspections. FDA plans on implementing pilot programs focused on evaluating the effect of conducting unannounced inspections and using independent translation services. However, these efforts have been delayed by the COVID-19 pandemic and the agency has not yet finalized the pilots' designs.

As FDA moves forward, the agency could benefit from incorporating leading practices for designing a well-developed and documented pilot program—such as developing a methodology that details the information necessary to evaluate the pilot. This would help ensure the pilots provide FDA with the information it needs to assess the value of unannounced inspections and independent translation services, and to decide whether these approaches should be applied more broadly to other foreign inspections.

While FDA has reduced vacancies among its general drug inspection workforce, FDA data showed that the agency still has persistent vacancies among those who specialize in foreign inspections as of November 2021. Specifically:

- eight of 20 positions were vacant in FDA's cadre of drug investigators that conduct only foreign inspections, and
- five of 15 drug investigator positions were vacant in its foreign offices located in China and India.

These are longstanding challenges that GAO has previously identified. According to FDA officials, foreign inspection work is challenging, requiring the investigator to work independently in a foreign establishment under constrained time frames. In 2020 and 2021, FDA began to take steps to identify new strategies to recruit and retain this workforce, but the agency has not yet detailed implementation steps and time frames. Fully developing such tailored strategies could help ensure FDA has the workforce needed to meet its global mission.